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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,896	03/11/2004	Eric D. Rabinovsky	AVSI-0034 (108328.00172)	7397

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EXAMINER	
DOWELL, PAUL THOMAS	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,896	RABINOVSKY ET AL.	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-40 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to an isolated nucleic acid expression construct comprising: i) a myogenic promoter, ii) a nucleic acid sequence encoding an insulin-like growth factor I (IGF-I) or functional biological equivalent thereof and iii) a 3' untranslated region (3'UTR); said isolated nucleic acid further comprising a transfection-facilitating system, classified in class 536, subclass 23.1.

II. Claims 17-38, drawn to a method for stimulating angiogenesis, or stimulating myogenesis, or elevating levels of an angiogenic factor, or stimulating endogenous production of an antiopoeitin, or treating a muscular or vascular complication of diabetes in a subject comprising delivering into a tissue of the subject said isolated nucleic acid expression construct, classified in class 514, subclass 44.

III. Claims 17 and 39, drawn to a method for elevating levels of a vascular endothelial growth factor (VEGF) having an amino acid sequence that is at least 85% identical to SEQ ID NO:7 comprising delivering into a tissue of a subject an isolated nucleic acid expression construct comprising: i) a myogenic promoter, ii) a nucleic acid sequence encoding an insulin-like

growth factor I (IGF-I) or functional biological equivalent thereof and iii) a 3' untranslated region (3'UTR), classified in class 514, subclass 44.

IV. Claims 17 and 40, drawn to a method for elevating levels of a vascular endothelial growth factor receptor (VEGF receptor) comprising delivering into a tissue of a subject an isolated nucleic acid expression construct comprising: i) a myogenic promoter, ii) a nucleic acid sequence encoding an insulin-like growth factor I (IGF-I) or functional biological equivalent thereof and iii) a 3' untranslated region (3'UTR), classified in class 514, subclass 44.

It is further note to Applicant that:

Upon election of groups I or II, Applicant's are further required to elect: either SEQID#1 or SEQID#2 as recited in claims 9-11, 15, 16 of group I and claims 24-26 of group II. It is noted that this is a restriction requirement and not a species election since the nucleic acids of SEQID#1 and SEQID#2 are structurally and functionally distinct and;

Upon election of groups II, III or IV, Applicant's are further required to elect: one goal of treatment from the group consisting of stimulating angiogenesis, stimulating myogenesis, elevating levels of an angiogenic factor, stimulating endogenous production of an angiopoietin, treating a muscular complication of diabetes or treating a vascular complication of diabetes. It is noted that this is a restriction requirement and not a species election since the instant treatment goals are distinct and;

Upon election of group II, Applicant's are further required to elect: one cell type from the group consisting of somatic cells, stem cells or germ cells as recited in claim 32. It is noted that this is a restriction requirement and not a species election since the different cell types recited in claim 32 are structurally and functionally distinct.

Groups I-IV are related as product (group I) and processes of use (groups II, III, IV). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, the nucleic acid and the nucleic acid further comprising a transfection-facilitating system of group I, can be used as a hybridization probe in a method comprising a step of hybridization and can be used in a method of expressing recombinant protein for purification.

Further, while the inventions of groups II, III and IV are related in being drawn to methods of treatment comprising delivering into a tissue of a subject an isolated nucleic acid expression construct comprising: i) a myogenic promoter, ii) a nucleic acid sequence encoding an insulin-like growth factor I (IGF-I) or functional biological equivalent thereof and iii) a 3' untranslated region (3'UTR), they are patentably distinct each from the other because the treatment goals are distinct. For example, group II is drawn to a method for any one of the following: stimulating angiogenesis, or stimulating myogenesis, or elevating levels of an angiogenic factor, or stimulating endogenous

production of an antiopoeitin, or treating a muscular or vascular complication of diabetes in a subject; while group III is drawn to a method for elevating levels of a vascular endothelial growth factor (VEGF) having an amino acid sequence that is at least 85% identical to SEQ ID NO:7; while group IV is drawn to a method for elevating levels of a vascular endothelial growth factor receptor (VEGF receptor). Because these are distinct and not entirely co-extensive goals of said methods, groups II, III and IV are distinct each from the other.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Dowell
Art Unit 1632

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER